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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,076	08/20/2003	Ulrich Luecking	SCH-1929	4728
23599	7590	02/15/2006	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			COLEMAN, BRENDA LIBBY	
		ART UNIT		PAPER NUMBER
				1624

DATE MAILED: 02/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/644,076	LUECKING ET AL.	
	Examiner Brenda L. Coleman	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 November 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 6,10 and 11 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-5,7-9 and 12-23 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/04/05 & 1/07/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claims 1-23 are pending in the application.

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on November 30, 2005 is acknowledged. The traversal is on the ground(s) that it would not be a burdensome search to search the full scope of the application. This is not found persuasive because first a macrocyclic compound of formula (I) where A is a C₃-C₁₂-arylene or C₃-C₁₈-heteroarylene are clearly structurally dissimilar compounds which are classified in various subclasses under classes 514 and 540.

(1) Note MPEP 2173.05(h) "where a Markush expression is applied only to a portion of a chemical compound, the propriety of the grouping is determined by a consideration of the compound as a whole, and does not depend on there being a community of properties in the members of the Markush expression. Therefore, what should be considered for patentable distinctness is the compound as a whole. Would a whole compound where A is phenylene, be patentably distinct from a whole compound where A is a thiophenylene? If a reference for one would not be a reference for the other, then restriction is considered proper. Community of properties is not enough to keep a macrocycle containing an additional ring such as phenylene, thiophenylene, pyridinylene, triazolylene, etc. in the same Markush claim, where the Markush expression is applied only to a portion of a chemical compound. It is the compound as a whole where instant A is phenylene, thiophenylene, pyridinylene, triazolylene, that must be considered for patentable distinctness.

Thus, separate searches in the literature would be required. However, should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

(2) The degree of burden on the examiner is high. The class/subclass search on the elected invention where ring A in the compounds of formula I is a phenylene ring would be as follows: class 514, subclasses 257 and 267; and class 540, subclasses 460, 469 and 472 which involved 1384 US patents. The classes and subclass mentioned above represent only the degree of burden within the U.S. Patent Classification System this does not include the search required in the prior art of journal articles and foreign patents.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 6, 10 and 11 as originally filed are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on November 30, 2005.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1624

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 12-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims where the compounds of formula I are used to inhibit cyclin-dependent kinases, CDK1, CDK2, CDK3, CDK4, CDK5, CDK6, CDK7, CDK8, CDK9, glycogen-synthase-kinase (GSK-3 β), VEGF-receptor tyrosine kinases, in addition to the treatment of a magnitude of neurodegenerative diseases, autoimmune disease, etc., the claims also include the treatment of cancer. Evidence involving a single compound and two types of cancer was not found sufficient to establish the enablement of claims directed to a method of treating seven types of cancer with members of a class of several compounds In re Buting 163 USPQ 689. The remarkable advances in chemotherapy have seen the development of specific compounds to treat specific types of cancer. The great diversity of diseases falling within the "tumor" category means that it is contrary to medical understanding that any agent (let alone a genus of thousands of compounds) could be generally effective against such diseases. The intractability of these disorders is clear evidence that the skill level in this art is low relative to the difficulty of the task.

Where the utility is unusual or difficult to treat or speculative, the examiner has authority to require evidence that tests relied upon are reasonably predictive of in vivo efficacy by those skilled in the art. See *In re Ruskin*, 148 USPQ 221; *Ex parte Jovanovics*, 211 USPQ 907; MPEP 2164.05(a).

Patent Protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Tossing out the mere germ of an idea does not constitute enabling disclosure. *Genentech Inc. v. Novo Nordisk* 42 USPQ2d 1001.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 1-5, 7-9 and 12-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 1-5, 7-9 and 12-23 are vague and indefinite in that a formula is not general when all of the variables are defined. Deletion of "general" is suggested.
- b) Claim 1, 2, 7, 9 and 12-23 are vague and indefinite in that it is not known what is meant by list of substituents on the moieties of B, where the substituents include the moiety phenyl-(CH₂)_p-R¹⁰, which fails to indicate the point of attachment and is valence satisfied.
- c) Claim 1-3, 7-9 and 12-23 are vague and indefinite in that it is not known what is meant by the definition of X and Y, where the moiety =NR¹¹- contains four bonds.

- d) Claim 1, 2, 7, 9 and 12-23 are vague and indefinite in that it is not known what is meant by the definition of R¹ and R⁵, where the moiety C₁-C₆-alkenyl. Alkenyl requires at least two carbon atoms.
- e) Claim 1, 2, 7, 9 and 12-23 are vague and indefinite in that it is not known what is meant by the definition of R¹ and R⁵, where the moiety C₁-C₆-alkinyl. Alkinyl requires at least two carbon atoms.
- f) Claim 1, 2, 7, 9 and 12-23 are vague and indefinite in that it is not known what is meant by the definition of R¹ and R⁵, which includes the moiety phenyl-(CH₂)_p-R¹⁰, which fails to indicate the point of attachment **and** is valence satisfied.
- g) Claim 1, 9 and 12-23 are vague and indefinite in that it is not known what is meant by the definition of R¹ and R⁵, where the moiety S(O)₂N=CH-NR⁸R⁹ fails to indicate the point of attachment.
- h) Claim 1, 2, 7, 9 and 12-23 are vague and indefinite in that it is not known what is meant by the definition of R³, which includes the moiety phenyl-(CH₂)_p-R¹⁰, which fails to indicate the point of attachment **and** is valence satisfied.
- i) Claim 1, 2, 7, 9 and 12-23 are vague and indefinite in that it is not known what is meant by list of substituents on the moieties of R³, where the substituents include the moiety phenyl-(CH₂)_p-R¹⁰, which fails to indicate the point of attachment **and** is valence satisfied.

- j) Claim 1, 2, 7, 9 and 12-23 are vague and indefinite in that it is not known what is meant by the definition of R⁹, R¹⁰ and R¹¹, which includes the variables R⁹ and R¹⁰.
- k) Claim 1, 2, 7, 9 and 12-23 are vague and indefinite in that it is not known what is meant by list of substituents on the moieties of R⁹, R¹⁰ and R¹¹, where the substituents includes the moiety phenyl-(CH₂)_p-R¹⁰, which fails to indicate the point of attachment **and** is valence satisfied.
- l) Claim 2 is vague and indefinite in that it is not known what is meant by the second period, which appears at the end of the claim.
- m) Claims 4 and 5 recite the limitation "-NR¹¹-" in the definition of Y. There is insufficient antecedent basis for this limitation in the claim.
- n) Claim 9 is vague and indefinite in that it is not known what is meant by "formula I". There is no formula I in claim 9.
- o) Claim 9 is vague and indefinite in that it is not known what is meant by "suitable acid".
- p) Claim 9 is vague and indefinite in that it is not known what is meant by "suitable solvent".
- q) Claim 9 is vague and indefinite in that it is not known what is meant by "suitable reducing agent".
- r) Claims 12, 13 and 18-23 provides for the use of the compounds of formula I, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to

encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

s) Claims 12-22 are vague and indefinite in that it is not known what is meant by "an agent" does not clarify whether the claim is limited to a compound, composition, or even complex composition.

t) Claims 12, 13 and 18-23 are substantial duplicates of claim 1. A statement of intended use is not given material weight. Note *In re Tuominen* 213 USPQ 89

u) Claims 15 and 16 are substantial duplicates of claim 14. A statement of intended use is not given material weight. Note *In re Tuominen* 213 USPQ 89

v) Regarding claims 12, 13, 15 and 16, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 12, 13 and 18-23 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App.

1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Brenda L. Coleman
Primary Examiner Art Unit 1624
February 10, 2006